

## Are claims made in orthodontic journal advertisements evidence-supported?

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### ABSTRACT

**Objective:** To examine the supporting evidence of advertisements published in six leading orthodontic journals.

**Materials and Methods:** The 2012–2013 printed issues of *American Journal of Orthodontics and Dentofacial Orthopedics*, *Australian Orthodontic Journal*, *Journal of Orthodontics*, *European Journal of Orthodontics*, *Journal of Clinical Orthodontics*, and *Journal of Orofacial Orthopedics* were screened for advertisements implying superior performance compared with competitor products. Advertisements were classified according to type of product, availability, and currency of supporting references.

**Results:** A total of 99 unique advertisements claiming clinical benefit or superiority were identified. The overwhelming majority of the identified advertisements promoted appliance products (62.6%), orthodontic materials (14.1%), and dental operatory equipment, including imaging systems (12.1%). Advertisements were found to provide references or not regardless of the product type. Half of the advertisements referred to at least one peer-reviewed publication, whereas unpublished studies were cited by 25% of the advertisements. Most of the referenced articles were published within the past 5 years.

**Conclusions:** The scientific background of advertisements in the orthodontic literature appears limited. While surveillance of journal advertising needs to be regulated, clinicians are urged to critically appraise the claims being made in orthodontic print advertisements by consulting the associated existing evidence. (*Angle Orthod.* 2015;85:184–188.)

**KEY WORDS:** Orthodontics; Evidence; Orthodontic journals

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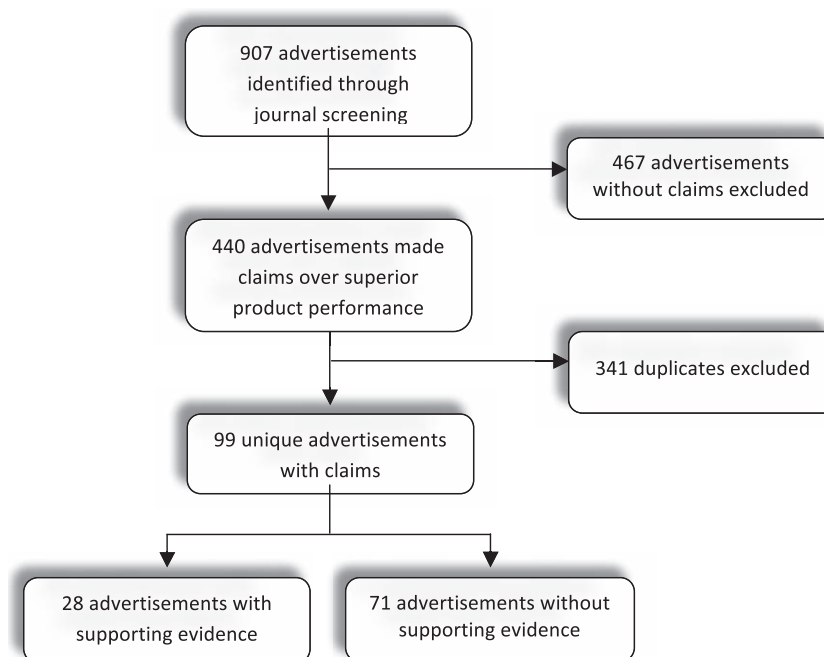
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### INTRODUCTION

There is evidence that dental practitioners select print journals as the second highest preferred information source following continuing education courses to support clinical decision making.<sup>1</sup> Most scientific journals regularly contain manufacturer advertisements intended to inform the clinicians about new or established products. Interestingly enough, even drug prescriptions can be influenced by scientific journal advertising.<sup>2</sup>

To increase credibility and acceptance by the target audience, promotional claims may be accompanied by references to supporting studies. Previous research has indicated that evidence citation in medical journal advertisements aimed to substantiate product claims ranged from 12%–76%.<sup>2–7</sup> Moreover, roughly 8 of 10 advertisements published in four major dental journals did not provide adequate peer-reviewed evidence to support the claims.<sup>8</sup> However, referenced advertising does not necessarily guarantee the quality of claims.<sup>2</sup>



**Figure 1.** Flowchart of the screening process.

In view of the potential for errors in presentation and irrelevance of advertisement references, health care professionals should be able to appraise whether a manufacturer's statements are adequately demonstrated.<sup>5</sup> In orthodontics, the evidence supporting the claims disseminated by journal advertisements has not been formerly evaluated. Therefore, the objective of this study was to determine the availability and type of evidence in support of advertisement claims in six leading orthodontic journals.

## MATERIALS AND METHODS

Advertisements appearing between January 2012 and December 2013 in *American Journal of Orthodontics and Dentofacial Orthopedics (AJODO)*, *Australian Orthodontic Journal (AOJ)*, *Journal of Orthodontics (JO)*, *European Journal of Orthodontics (EJO)*, *Journal of Clinical Orthodontics (JCO)*, and *Journal of Orofacial Orthopedics (JOO)* were identified for the purposes of the study. We originally planned to investigate the content of two more impact factor orthodontic journals, *The Angle Orthodontist* and *Orthodontics & Craniofacial Research*, but because of complete lack of advertisements, both were excluded. The journals of choice were selected on the basis of peer-review process, geographical origin, print circulation, and pageviews figures, as these were provided by journal Web sites. Furthermore, all journals are endorsed by or represent official publications of national and international orthodontic societies. In total, 60 print journal issues and supplements

published within the 2-year period were scrutinized. Advertisements implying superior product performance on clinical practice or patient care<sup>9</sup> were selected for further evaluation. Details regarding the type of advertised product, availability, types, and currency of references included were recorded. Advertisement versions promoting the same product were classified as unique in cases in which the supporting reference was not the same. In the presence of a supporting citation, PubMed indexing of the reference article was examined. Conference abstract references were regarded as unpublished studies.

## Data Analysis

Descriptive statistics were used to illustrate the presence and nature of evidence supplied by advertisers to support performance statements. The Fisher's exact test of independence was performed to determine the association between the type of product and availability of supporting evidence. Statistical analysis was implemented with the STATA version 13.1 software (Stata Corporation, College Station, Tex).

## RESULTS

### Selected Advertisements

Initial hand searching of 26 *AJODO*, 4 *AOJ*, 12 *EJO*, 24 *JCO*, 9 *JO*, and 11 *JOO* issues yielded 907 advertisements. After exclusion of advertisements lacking statements on product benefits and duplicates, 99 items remained (Figure 1). Of these advertisements,

**Table 1.** Distribution of Advertisements Claiming Superior Product Performance According to Evidence Availability and Product Type

Product Type	Evidence Availability		Total (n)	Total (%)
	No (n)	Yes (n)		
Appliances	44	18	62	62.6
Materials	12	2	14	14.1
Other device <sup>a</sup>	8	4	12	12.1
Device for patient use	2	2	4	4.0
Mini-implants	3	0	3	3.1
Software	1	2	3	3.1
Mouth rinse	1	0	1	1.0
Total	71	28	99	100.0

<sup>a</sup> Scanner, dental unit, radiographic equipment, curing light, whitening system, laser system.

only 28 of 99 (28.3%) added references to strengthen the manufacturer's argument. Interestingly, five single products appeared in commercials with and without references; in three of these cases, more than one type of supporting evidence was included such as peer-review article, expert opinion, and so on. For the remaining 71 advertisements, no citations were included in support of the claims made. One of the journals (*AOJ*) summarized in a special section of each issue the newly advertised products, reproducing without endorsement the manufacturers' claims.

### Product Category and Evidence Availability

The distribution of advertisements according to the advertised product category is presented in Table 1. Orthodontic appliances (62.6%), orthodontic materials (14.1%), and devices including scanners, curing lights, and radiographic equipment (12.1%) were the top categories of advertisements claiming superiority in terms of clinical features and patient comfort. Fisher's exact test showed that there was no association between advertisements providing evidence and product category ( $P = .39$ ).

### Type and Currency of Evidence

With regard to the type of evidence, 11 of the 28 references included at least one full-text article publication, whereas data on file (ie, proprietary information that companies are not obligated to report, in-house unpublished studies, or conference abstracts) were cited by 25% of the advertisements (Table 2). Of these articles, six investigated treatment appliance efficiency, three oral hygiene device efficiency, one esthetics, and one diagnostics. An expert's statement regarding personal experience on product performance was used in six commercials. Moreover, a layperson's opinion was added to a PubMed citation in one of the advertisements. Two identified commercials provided irrelevant article references. The adver-

**Table 2.** Distribution of Advertisements According to Type of Supporting References

Type of Supporting Evidence	Number of Advertisements
Article(s)	6
Unpublished study(ies)	7
Expert's opinion	6
Combination including article(s)	5
Combination without an article	4
Total	28

tisers of three products, namely, a tooth-whitening system, a micropulse generator, and an oral hygiene appliance, clearly stated that their statements had not been at that time substantiated by peer-reviewed research. Finally, 8 of the 11 reference articles were published within the past 5 years.

### DISCUSSION

Identification and use of reliable, current scientific evidence plays a central role in the practice of evidence-based dentistry.<sup>1</sup> While many clinicians consult advertisements on the latest treatment innovations, they should be aware that motives other than providing information may hide behind manufacturers' true intentions. After all, the primary purpose of advertisements is to increase the sales of new products or maintain sales of established products.<sup>10</sup> Likewise, profit-driven marketing policies of drug and device manufacturers promote presentation of research findings through advertisements in an effort to persuade prospective clients. Such promotional strategies may add an impression of authenticity rather than communicate the evidence behind product claims.<sup>11</sup> Under these circumstances, a critical attitude toward journal advertising appears justified.

Our study demonstrates that less than one-third of orthodontic journal commercials supplied references to defend claims of product performance and superiority, which matches favorably with the findings of a recent dental study.<sup>8</sup> No patterns in evidence availability based on the type of promoted product were observed. We further found that 50% of the supporting evidence referred to peer-reviewed articles, primarily published within the past 5 years. Similar studies in medical and dental journals concluded that the published scientific articles accounted for 18%–76% of supporting claims, with the lowest incidence emerging in dental literature advertisements.<sup>3,5,7–9</sup> In two cases that included article references, the study design did not concern performance testing of the product of the advertisement itself, and therefore, the study was considered irrelevant. These manufacturers either implemented as stated the methodology of the investigation of three other intraoral scanners or used a general reference on the influence of the slot size in biomechanics to

justify the design of the bracket of interest. Mislabeling of references may also theoretically occur. Fourteen to sixteen percent of the references cited by advertisements in German and Swiss dental journals could not be identified.<sup>12</sup> We found that in three advertisements, the identity of conference abstract references was not disclosed. Inappropriate translation of study conclusions to fit the advertiser's message has been also described. Even in the presence of the highest level of evidence, advertisements tended to extrapolate randomized clinical trial results to other patient groups, dosages, or treatments.<sup>6</sup>

The relatively high frequency of "data-on-file" references may be due to the eagerness of manufacturing companies to advertise for new indications for which the data have not yet been published in the public literature.<sup>6</sup> Nonetheless, data-on-file references on advertisement copies should not a priori be interpreted as access to readily available records. As stated by the World Health Organization,<sup>13</sup> access to scientific data in the public domain, when requested, should be facilitated for prescribers or other concerned parties. In contrast, Cooper and Schriger<sup>5</sup> received from manufacturers only 20% of the data-on-file references upon request. It is noteworthy that half of the pharmaceutical companies that responded to the authors' requests for data on file denied handing over in-house study data because of proprietary information or company policy reasons.<sup>5</sup> In addition, potential interference of sponsorship or funding selective outcome reporting and consequent bias should not be neglected. Studies funded by the pharmaceutical industry were more likely to announce favorable outcomes for the sponsoring company than research supported by other granting agencies.<sup>14</sup>

In 9 of 28 advertisements, a positive personal experience statement was used solely or in combination with another type of evidence to support the product's superior performance. A survey among orthodontists was cited to support the statement of improved clinical outcomes with the use of the innovative technology of transparent splints. Clinical photographs obtained at the start and at the end of treatment, occasionally with the name of the operator-practitioner, were posted on five advertisements. Nevertheless, in all but two advertising copies, no patient photographs with the appliances advertised in place were included. Images of different magnification of vacuum-formed removable appliances were displayed side by side to confirm the esthetic superiority of finishing of the advertised product. Manufacturers of orthodontic materials further highlighted the superior properties of an elastomeric chain compared with competing products, as this was documented by "numerous" but not cited "independent clinical tests."

Advertisers were also keen on using phrases to stress the evidence availability on the proven performance of their products, even in cases of untraceable or nonoperative link sources. Lastly, besides the traditional display of attractive models with full smiles, cartoon figures were recruited to illustrate the product's effectiveness.

Medical marketing and advertising need to be regulated to prevent misrepresentation of product features and performance. In the past, reviewers of pharmaceutical ads in medical periodicals encountered deficiencies even in areas in which the Food and Drug Administration (FDA) had established explicit quality guidelines.<sup>15</sup> With reference to orthodontics, a number of orthodontic appliances and attachments are assigned to Class I devices according to FDA classification: devices posing the lowest risk to patients and exempt from the premarket notification procedures. Manufacturers are required only to register their establishment and list the generic category or classification name. This group of devices, coded as 872.5410, comprises preformed metal and elastic bands, band materials, metal brackets, wire clamps, preformed space maintainers, orthodontic expansion screw retainers, springs, tubes, and archwires.<sup>16</sup> It is unfortunate that intergovernmental regulatory bodies such as the Global Harmonization Task Force, although being involved in all aspects that have direct impact on the safety and performance of medical devices, do not place advertising demands on manufacturing companies.

In real-life clinical practice, because of lack of time, readers might take for granted advertisement statements without looking into the reliability and accuracy of the supporting evidence.<sup>9</sup> High-profile periodicals are expected to run meticulous review procedures not only for research articles under submission but advertisements as well. Well-defined guidelines may address space limitations of the advertising format and enable proper presentation of validity, significance of results, and applicability to clinical practice.<sup>17</sup> Lack of publication references to prove the advertisement claims may be partly compensated by inclusion of a clear "not yet verified by peer-reviewed research" statement, as a few orthodontic manufacturers did in this study. Despite the fact that 40% of North American medical journal editors were in favor of subjecting pharmaceutical advertisements to the same rigorous peer review as scientific articles, this did not occur in practice.<sup>18</sup> Undoubtedly, nearly all medical journals rely to some extent on advertising revenue to manage high publishing costs, and absolute elimination of commercials may be unrealistic, especially for small journals. On the other hand, alternative revenue sources may include fund-raising campaigns and donations,



subscriptions, publication fees for accepted research papers, and advertising of products not related directly to clinical practice, such as management and marketing services.

This study presents specific shortcomings. Analysis was limited to six journals, five published in English and one bilingual, and examined 2 years of publication. A more comprehensive review expanding the number of periodicals, language, and years of publishing might have traced different trends. Hypothetically, choosing a longer observation period could have increased the pool of results but not necessarily the significance of conclusions, as advertisements of obsolete products might have been identified. No attempt was made to contact manufacturers to obtain full records of data-on-file references. Yet, based on the previous unwillingness of pharmaceutical companies to provide research material referenced by advertisements,<sup>5</sup> it is unlikely that requests for data-on-file information would have changed the results.

The vast majority of advertisements in the orthodontic literature do not provide supporting data directly available to readers. Clinicians should be able to critically appraise the content of advertisements. Further improvement of surveillance mechanisms will ensure that journal ads provide proper product promotion and consumer protection. Enhanced accessibility to and censoring of the validity of the orthodontic journal advertisements may reinforce evidence-based decision making in clinical orthodontics.

## CONCLUSIONS

- Evaluation of a representative sample of orthodontic journal advertisements showed that less than one-third of commercials provided references to support product claims. The claims supporting evidence included peer-reviewed publications in only half of the advertisements with references.
- Based on the limited evidence availability in support of advertisement statements, orthodontists should be cautious in taking at face value manufacturers' recommendations for clinical practice.

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